CLINICAL RESEARCH PROTOCOL **CONTINUING** REVIEW APPLICATION

PROTOCOL NO.

PRINCIPAL INVESTIGATOR(Print or Type Name):

PROTOCOL TITLE:

ACTION REQUESTED:
- ☐ Renew -New subject accrual to continue
- ☐ Renew -Enrolled subject followup only
- ☐ Terminate -Protocol discontinued (describe briefly in the attached narrative.)

HAVE THERE BEEN ANY AMENDMENTS SINCE THE LAST REVIEW?
- ☐ No
- ☐ Yes (Describe briefly in the attached narrative)

SUMMARY OF PROTOCOL SUBJECTS:
- _____ Accrual ceiling set by IRB
- _____ New subjects accrued since last review
- _____ Total subjects accrued since protocol began (If accrual has been less then expected, discuss in the attached narrative)

ACCRUAL EXCLUSIONS:
- ☐ None ☐ Male
- ☐ Female ☐ Other _____

IMPAIRED SUBJECTS:
- ☐ None ☐ Physically ☐ Cognitively

HAVE THERE BEEN ANY CHANGES IN THE SUBJECT POPULATION, RECRUITMENT OR SELECTION CRITERIA SINCE THE LAST REVIEW?
- ☐ No
- ☐ Yes (Explain changes in the attached narrative)

HAVE THERE BEEN ANY CHANGES IN THE INFORMED CONSENT PROCESS OR DOCUMENTATION SINCE THE LAST REVIEW?
- ☐ No
- ☐ Yes (Explain changes in the attached narrative)

HAS ANY INFORMATION APPEARED IN THE LITERATURE, OR EVOLVED FROM THIS OR SIMILAR RESEARCH, THAT MIGHT AFFECT THE IRB's EVALUATION OF THE RISK /BENEFIT ANALYSIS OF HUMAN SUBJECTS INVOLVED IN THIS PROTOCOL?
- ☐ No
- ☐ Yes (Discuss in the attached narrative)

HAVE ANY UNEXPECTED COMPLICATIONS OR SIDE EFFECTS BEEN NOTED SINCE LAST REVIEW?
- ☐ No
- ☐ Yes (Identify and explain in the attached narrative)

HAVE ANY SUBJECTS WITHDRAWN FROM THIS STUDY SINCE THE LAST IRB APPROVAL?
- ☐ No
- ☐ Yes (Discuss in the attached narrative)

CHANGE IN PRINCIPAL INVESTIGATOR:
- ☐ None
- ☐ Delete: _____.
- ☐ Add: _____.

HAVE ANY ASSOCIATE INVESTIGATORS BEEN ADDED OR DELETED SINCE LAST REVIEW?
- ☐ No
- ☐ Yes (Identify all changes in the attached narrative)

CHANGE IN MEDICAL ADVISORY INVESTIGATOR:
- ☐ None
- ☐ Delete: _____
- ☐ Add: _____

CHANGE IN RESEARCH CONTACT: ☐ No ☐ Yes

_____
Name (Degree) Address

_____
Telephone FAX e-mail

INVESTIGATIONAL NEW DRUG/DEVICE
- ☐ None ☐ IND ☐ IDE

FDA No. _____

Name _____.

Sponsor _____.

Holder _____

HAVE ANY NON-NIH INVESTIGATORS OR SITES BEEN ADDED SINCE THE LAST REVIEW?
- ☐ No
- ☐ Yes (Identify the persons or sites and describe the collaboration in the attached narrative)

IONIZING RADIATION USE (X-rays, radioisotopes, etc.):
- ☐ None
- ☐ Medically indicated only
- ☐ Research indicated:
  - ☐ Research usage HAS NOT changed since originally approved by the IRB and RSC
  - ☐ Research usage HAS changed since originally approved by the IRB and RSC (explain changes in the attached narrative)

HAVE ANY INVESTIGATORS DEVELOPED AN EQUITY OR CONSULTATIVE RELATIONSHIP WITH A NON-NIH SOURCE RELATED TO THIS PROTOCOL WHICH MIGH BE CONSIDERED A CONFLICT OF INTEREST?
- ☐ No
- ☐ Yes (Append a statement of disclosure)

The Principal Investigator must attach to this application: (1) a copy of the current consent/assent documents and (2) a memorandum to the IRB Chairperson that addresses any "yes" responses to the above questions, and that includes a concise statement regarding protocol progress to date and reason(s) for continuing the study.

SIGNATURE	_____ Principal Investigator	Date_____	Send to Accountable Investigator
RECOMMENDATION	_____ Accountable Investigator	Date_____	Send to Branch Chief, or CC Department Head of Principal Investigator
	_____ Branch Chief, or CC Dept. Head of P.I.	Date_____	Send to Clinical Director
APPROVALS	_____ Clinical Director	Date_____	Send to Chair, Institutional Review Board
	_____ Chair, Institutional Review Board	Date_____ Protocol and Consent Approved Effective	Send to Protocol Coordination Service Center, MRD (10/1N208) through IRB Protocol Coordinator
COMPLETION	_____ Protocol Specialist	Date_____	